PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference G103010WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/004305	International filing date (*day/month/year*) 03 April 2003 (03.04.2003)	Priority date (*day/month/year*) 14 February 2003 (14.02.2003)
International Patent Classification (IPC) or national classification and IPC C07K 1/113, 7/06, 7/08, G01N 33/68, 27/62		
Applicant SHIMADZU CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
12 September 2003 (12.09.2003)	10 March 2004 (10.03.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/004305

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 9-10

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 9-10 are so unclear that no meaningful opinion could be formed *(specify)*:

With regard to the "novel compounds respectively containing a peptide found by eliminating the phosphoric acid group of the peptide" and "candidate compounds for drugs developed from the novel compounds" described in claims 9 and 10, what compounds are included in addition to the particularly obtained compounds and what compounds are not included are quite unknown, even considering the description of the specification. So, the description of claims 9 and 10 is very unclear.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 9-10 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 6-8	YES
	Claims	1, 3-5	NO
Inventive step (IS)	Claims		YES
	Claims	1-8	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations

Document 1: M. A. Smith, et al., Brain Research, 1996, Vol. 717, pages 99-108, whole document, especially see Table 2.
Document 2: JP, 10-90226, A (Shimadzu Corp.), 10 April, 1998 (10.04.98), see the whole document.
Document 3: WO, 01-78106, A2 (PerSeptive Biosystems, Inc.), 18 October, 2001 (18.10.01), see the whole document.

Document 1 describes to the effect that if PHF protein is treated with 50% hydrofluoric acid at room temperature, dephosphorylation occurs.

Document 2 describes a method for deciding the amino acid sequence of a peptide, comprising the steps of (1) bonding an amino acid having charges to an end of the peptide molecule to be analyzed, (2) ionizing the peptide molecule having the amino acid bonded while generating decomposition ions, and (3) separating and detecting these ions by mass spectrometry. It is also described that (1) Matrix Assisted Laser Desorption Ionization (MALDI) is used as the said ionization method, and (2) Time-of-Flight Mass Spectrometry (TOFMS) is used as the said mass spectrometry.

Document 3 describes to the effect that an apparatus provided with MALDI and TOFMS is used for analysis using a mass spectrometer.

Document 1 describes to the effect that PHF protein is made to react at room temperature using 50% hydrofluoric acid, for dephosphorylation. So, the subject matters of claims 1 and 3-5 do not appear to be novel. Furthermore, selecting optimum reaction conditions is usually practiced by a person skilled in the art.

It was publicly known before the priority date of the present application that when the amino acid sequence of a peptide is decided, (1) the peptide molecule is ionized using Matrix Assisted Laser Desorption Ionization (MALDI) and (2) the said ions are separated and detected by Time-of-Flight Mass Spectrometry (TOFMS), as described in document 2. An analyzer provided with MALDI and TOFMS was also publicly known before the priority date of the present application, as described in document 3. So, when the amino acid sequence of a phosphorylated peptide is decided, a person skilled in the art could have easily conceived of (1) treating the phosphorylated peptide using hydrofluoric acid, for dephosphorylation, and (2) deciding the amino acid sequence using MALDI and TOFMS.

Therefore, a person skilled in the art could have easily conceived of the subject matters of claims 1-8 based on documents 1 and 3.